K120789

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR EXACTRAC

AUG 14 2012

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	June 11, 2012
Device:	ExacTrac
Trade name:	ExacTrac® X-Ray, ExacTrac® Infrared Monitoring, ExacTrac® IGRT, ExacTrac® Snap Verification, ExacTrac® Room-based IGRT, ExacTrac® CBCT Alignment
Common/Classification Name:	Patient Positioning System with respiratory Gating, Radiation Therapy, Charged-Particle, Medical
Predicate Device:	ExacTrac 5.5 (K072506) Varian On-Board Imager Device (K042720)
Device classification name:	System, Radiation Therapy, Charged-Particle, Medical
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.5050
Product Code:	IYE
Indication for use	ExacTrac is intended to be used to place patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. ExacTrac may also be used to monitor the patient position during the treatment.

Device description:	ExacTrac is a patient positioning and monitoring system providing the following main features:
	• Patient positioning based on comparison between ExacTrac acquired X-ray images and calculated DRR (Digital Reconstructed Radiographs) using data provided by a treatment planning system.
	• Patient positioning based on comparison between a CBCT scan, acquired by a 3rd Imaging Device and imported into ExacTrac, and CT data provided by a treatment planning system.
	• Both modalities can be based on:
	  ○ anatomical landmarks
	  ○ implanted markers
	• Patient monitoring during treatment

margins i.e. 4x or 8x its weight
- Heat resistance tests to make sure that the material does not change due to a change in temperature e.g. as a result of sterilization
- Biocompatibility tests
- Prototyping
- EMC testing in accredited laboratory

Statement of the clinical test:

For the Clinical Evaluation the following validation methods and data sources have been used:
- Literature review
- Simulated treatment of anthropomorphic human-bone phantoms within a real clinical environment
- Analysis of existing x-ray image datasets acquired with ExacTrac 5.5 during routine clinical use
- Analysis of existing CBCT datasets during routine clinical use for retrospective clinical study.

Application performance testing

On different levels of development (module, subsystem, system) specific bench and integration tests were conducted. Internal standards were tested and documented as conformance report, environment compatibility and interfaces. Compatibility with previous version and comparable workflows to predicate devices were documented in corresponding review protocols.

Conclusions

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Alexander Schwiersch
Regulatory Affairs Manager
BrainLab AG
R&D Radiosurgery
Kapellenstrabe 12
FELDKIRCHEN BAVARIA 85622
GERMANY

AUG 14 2012

Re: K120789
Trade/Device Name: ExacTrac
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 12, 2012
Received: June 18, 2012

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K120789

Device name: ExacTrac

Indication for use:

ExacTrac is intended to be used to place patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. ExacTrac may also be used to monitor the patient position during the treatment.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD

510k K120789